K110769

STERIS®

JUN - 3 2011

510(k) Summary
For
Amsco Warming Cabinet
Mid-size Model

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Summary Date: May 3, 2011

1. Device Name

Trade Name:	Amsco Warming Cabinet, Mid-size Model
Common/usual Name:	Warming Cabinet
Classification Name:	Warmer, Thermal, Infusion Fluid; Unclassified, Product Code LGZ

2. Predicate Device

Amsco Warming Cabinet (K092823)

3. Description of Device

The Amsco Warming Cabinet is designed to store and warm sterile IV solutions, surgical irrigation solutions, linens and/or blankets to an acceptable level for hospital and surgical outpatient center applications.

The mid-size model consists of a single chamber unit and is available in (4) saleable configurations all with premium features (24" deep, glass door, electronic door lock, data recording and 120 or 230Vac with or without option mobile base). Optional pull-out wire baskets can be interchangeable with the existing wire shelf. Each of the two wire baskets have a 30L maximum capacity. The external measurements are 36-3/8"H x 27-1/8"D x 30"W (without mobile base) and the internal heat compartment is 22-3/4"H x 22-7/8"D x 24"W (7.2 cu ft).

4. Intended Use

The Amsco Warming Cabinet is designed to raise the temperature of blankets, linens and sterile surgical irrigation solutions and IV solutions to an acceptable level for various surgical, obstetrical, emergency, critical care and other healthcare applications.

5. Description of Safety and Substantial Equivalence

Substantial Equivalence

The Mid-size Amsco Warming Cabinet is identical in technology and intended use as the predicate Amsco Warming Cabinet models. A table comparing the proposed Amsco Warming Cabinet model to the predicate models is provided in Table 5-1.

Table 5-1: Summary of the Proposed Device and Predicate Devices Technological Characteristics

Features	PREDICATE Amsco Warming Cabinet (K092823)	PROPOSED Amsco Warming Cabinet Mid-size Model
Intended Use	The Amsco Warming Cabinet is designed to raise the temperature of blankets, linens and sterile surgical irrigation solutions and IV solutions to an acceptable level for various surgical, obstetrical, emergency, critical care and other healthcare applications.	Identical
Heating System	Electric heater and fan blower (Convection heating)	Identical
Unit Configuration	Single/Double chamber	Single chamber
Unit Depth	18" or 24"	24"
Model	Freestanding, mobile base (24" dual chamber only), or Counter (single chamber only)	Freestanding or mobile base
Interior and Exterior Surfaces	Stainless Steel, ABS Plastic and laminated galvanized steel	Identical
Installation	Free-Standing, Recessed, Mobile (24" dual chamber only), or Counter (single chamber only)	Free-Standing, Mobile, Recessed, or Under Counter
Door	Laminated steel exterior and Stainless Steel interior (Solid and Glass)	Laminated steel exterior and Stainless Steel interior (Glass)
Cabinet Storage Capacity and Volume	18" upper / single chamber - 3.2 cu ft – up to 24 (1-liter) bottles 18" lower chamber - 8.5 cu ft – up to 72 (1-liter) bottles 24" upper / single chamber - 4.3 cu ft – up to 30 (1-liter) bottles 24" lower chamber - 11.6 cu ft – up to 90 (1-liter) bottles	7.2 cu ft – up to 60 (1-liter) bottles

Features	PREDICATE Amsco Warming Cabinet (K092823)	PROPOSED Amsco Warming Cabinet Mid-size Model
Controls	Digital Push Button keypad / power switch / Digital LCD temperature display / mode selection buttons / door ajar indicator / Over-temperature light for each compartment / Data port for retrieval of stored temperatures.	Identical components as the Predicate: Digital Push Button keypad / power switch / Digital LCD temperature display / mode selection buttons / door ajar indicator / Over-temperature light for compartment / Data port for retrieval of stored temperatures.
Software	Unit contains software	Identical - no changes were made to the software
Temperature Selection Range	90°F (32°C) to 160°F (71°C)	Identical
Temperature Lock	Temperature lock-out function to prevent unauthorized temperature changes.	Identical
Door Lock	All configurations will be equipped with either a manual mechanical door lock or optional electronic door lock system for each compartment	All configurations will be equipped with an electronic door lock system
Over Temperature Alarm Point	Visual and audible alarm if unit has a chamber temperature greater than 10°F (5.5°C) above set temperature. In the event of an over temp condition, sensors automatically turns off the heater(s).	Identical
Voltage Requirements	110/120 Vac, 220/240 Vac nominal, 50/60 HZ	Identical

Safety and Effectiveness

Table 5-2 summarizes the verification and validation activities that were performed to ensure that modifications do not affect the safety or effectiveness of the Amsco Warming Cabinet.

Table 5-2: Summary of Verification and Validation Activities for Mid-size Single Compartment Warming Cabinet

Test Description	Acceptance Criteria	Results
Electrical Testing	• Achieve passing results thru automated dielectric strength tester • Earth and Enclosure Leakage Current must not exceed requirements listed in UL 61010-1 clause 6.3.1b (must not exceed .5mA normal condition and 3.5mA single fault condition) • Ground bond must not exceed 0.1 ohm and maintain ground continuity. • The power input of equipment at rated voltage and steady state current shall not exceed the marked rating by 10%.	**PASS**
System Functions: Controls, Heating, Door Lock System Test	• Exhaust fans and blowers must operate continuously when the main power is set to the ON position • Opening or closing the doors shall not cause fans or blowers to turn off • Input current must be within 5.9 – 7.12 Amps for 120Vac unit. • Over-temp alarm must activate and displayed temperature flashes alternately with the error "Hi" when compartment temperature is more than 10°F above set point temperature • Warming cabinet must communicate with laptop or personal computer to transfer stored temperature data to the computer • Numeric code entered on keypad must unlock the door within 4 seconds. • Door must remain locked when 40 pounds of force is applied	**PASS**
Spillage	• Pass dielectric strength test per UL 610100-1, section 6, clause 6.8 • Voltage measurement of cabinet outer surfaces must not exceed test voltages per UL 61010-1, section 6, clause 6.3.2a.	**PASS**
Heating Performance (empty compartment)	• Temperature reading of each thermocouple must not vary from set-point temperature by more than ±3°F for temperature settings between 90-110°F and ±5°F for temperature settings between 110-160°F. • Normal system operation is maintained without over-temperature condition or faults occurring.	**PASS**
Heating Performance (Full IV solution load – upper and lower wire baskets)	• Temperature reading of each thermocouple must not vary from set-point temperature by more than ±3°F for temperature settings between 90-110°F . • Controls temperature display must reach set-point within 12 hours. • Normal system operation is maintained without over-temperature condition or faults occurring.	**PASS**

Test Description	Acceptance Criteria	Results
Heating Performance (Full irrigation solution load – upper and lower wire baskets)	• Temperature reading of each thermocouple must not vary from set-point temperature by more than ±3°F for temperature settings between 90-110°F and ±5°F for temperature settings between 110-160°F • Controls temperature display must reach set-point within 12 hours. • Normal system operation is maintained without over-temperature condition or faults occurring.	**PASS**
Heating Performance (Full irrigation solution load – upper wire basket) (Full blanket load – bottom shelf)	• Temperature reading of each thermocouple must not vary from set-point temperature by more than ±3°F for temperature settings between 90-110°F and ±5°F for temperature settings between 110-160°F • Controls temperature display must reach set-point within 12 hours. • Normal system operation is maintained without over-temperature condition or faults occurring.	**PASS**
Drop Test	• Pass dielectric strength test per UL 61010-1, section6, clause 6.8 • No damage that allows access to electrical live parts • No damage to the enclosure that could cause a safety hazard • No damage that could cause spread of fire • No damage to insulation of internal wiring	**PASS**
Stability Test	• No overbalance during test	**PASS**
Wire Basket Load and Force Test	• No catastrophic failure at 125 pounds. • No catastrophic failure at 105 pounds with the sliding of wire basket in a back and forward horizontal motion for at least 100 cycles.	**PASS**
ETL/cETL Code Compliance	• Meet UL 61010-1 Standard for Safety Electrical Equipment for Measurement, Control, and Laboratory Use. • Meet CAN/CSA C22.2 61010-1 Standard for Safety Electrical Equipment for Measurement, Control and Laboratory Use.	**PASS**

Conclusion

Verification and validation testing demonstrate that the proposed Amsco Warming Cabinet, mid-size model, operates as intended and is as safe and effective as the predicate. The differences between the proposed and predicate device are limited to the described modifications of the device and these proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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JAN 1 0 2017

Re: K110769
Trade/Device Name: Amsco Warming Cabinet, Mid-size Model
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: May 3, 2011
Received: May 4, 2011

Dear Mr. Sullivan:

This letter corrects our substantially equivalent letter of June 3, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
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Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Amsco Warming Cabinet

Indications For Use:

The Amsco Warming Cabinet is designed to raise the temperature of blankets, linens and sterile surgical irrigation solutions and IV solutions to an acceptable level for various surgical, obstetrical, emergency, critical care and other healthcare applications

Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

6/2/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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